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Medical Focus - Avian Flu Essentials

November 29, 2005

"Few things help an individual more than to place responsibility upon him, and to let him know that you trust him." – Booker T. Washington

Dear Colleague:

In the sixth letter in the Avian Flu Essentials series, I will delve into production issues involving vaccine and antiviral treatments.

Egg-based H5N1 vaccines are manufactured utilizing extremely lengthy techniques. Eleven day old fertilized chicken eggs are injected with the reference viral strain that has been modified to be less virulent. Other components are then added to help the viruses grow. Next, the viruses are harvested, purified, and inactivated so that the vaccine can be made. This process takes at least six months and relies on a continuous egg supply.

On the other hand, the seed strain can be injected directly into cell cultures using the cell based vaccine method. The viruses would still need to be harvested, purified and inactivated. The potential advantage is a faster ability to increase production. In addition, allergies to egg albumin could be prevented with this technique. However, finding a proper cell line to grow the virus in and adequately monitoring rapidly growing cell lines can prove to be a challenge.

In order to encourage vaccine research and more rapid production techniques, additional funding is needed, along with liability reform. Laws need to be in place to shield manufacturers from scientifically unfounded injury claims. There are existing programs to monitor for adverse reactions such as the CDC Vaccine Safety Datalink that help ensure the safety of new vaccines.

If a pandemic occurs, antiviral treatments can serve as a first line of defense. Additional studies on their effectiveness and support for antiviral production capacity will enhance our preparedness. Promoting licensing agreements can allow other manufacturing companies to produce this treatment with proper institutional expertise. Simply breaching a company's intellectual property rights would actually provide a disincentive for research. Furthermore, adequate facilities would not be in place to rapidly accomplish these manufacturing processes.

An article excerpt on the reverse side of this letter describes active research and careful exploration of new vaccines. For that reason, incentives need to be in place so that the United States can develop vaccine and antiviral manufacturing capacities by having the proper infrastructure at hand.

Sincerely,

Michael C. Burgess, M.D.
Member of Congress

Excerpt from The Cincinnati Enquirer, *Children's Hospital tests bird flu vaccine, Medical center one of four U.S. study sites*, November 10, 2005:

AVONDALE - Cincinnati Children's Hospital Medical Center is one of four sites in the United States testing a vaccine that could protect millions against a bird flu pandemic.

The vaccine, manufactured by sanofi pasteur, based in Swiftwater, Pa., is being administered locally to about 60 healthy older adults and 60 healthy children, said Dr. David Bernstein, director of infectious diseases at Cincinnati Children's.

Nationally, 450 children and adults will be recruited for the trial. Sanofi pasteur was awarded a $100 million contract by the U.S. Department of Health and Human Services this year to produce bulk vaccine against bird flu.

Cincinnati Children's began giving out the vaccine Oct. 31.

No vaccine exists for bird flu, although at least two are being tested.

Sanofi pasteur is also conducting studies of its vaccine in France and Australia.

"If there is a pandemic from this bird flu, the estimates are in the millions for lives that could be lost," Bernstein said. "It would easily overwhelm the medical system."
It's almost impossible to give a time frame on when the vaccine could be on the market.
"There are so many variables to consider," John Abrams, a spokesman for sanofi pasteur, said.

Those variables include possible health complications, licensing by the U.S. Food and Drug Administration and manufacturing capacity. And it's possible that H5N1, the virus the vaccine is based on, will never become a widespread threat. Viruses mutate, and another form of avian flu could evolve to become a threat.

But if it does, the vaccine will be used.

"If we had to use it tomorrow, we would use it," said Bill Hall, a Washington-based spokesman for the U.S. Department of Health and Human Services.

If the vaccine is approved and a need for it is identified, Bernstein said, the vaccine could be available within three months after that point.

Double-blind study

At Cincinnati Children's, the trial is a placebo-controlled, double-blind study, meaning that volunteers don't know whether they received the bird flu vaccine or a placebo.

None of the volunteers has complained of ill effects, said Vicki Smith, a registered nurse and study coordinator. Volunteers are being recruited from previous vaccine trials and are being paid $40 a visit to cover time and travel costs. If they complete the trial, each will receive another $100.

Each volunteer receives a primary vaccination and two boosters over a six-month period. They will be tracked for one year for signs of health problems, such as immune disorders or allergic reactions.

A previous trial of the vaccine at other centers showed it to be safe in healthy adults, Bernstein said. The current trial examines the vaccine's safety and how long it might provide protection against bird flu in those most at risk for complications: seniors and young children.